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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,343	02/12/2004	Salvador Marquez	ECV-5622CON	4931
30452	7590	09/06/2005	EXAMINER	
EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,343

Applicant(s)

MARQUEZ, SALVADOR

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-24, 27-30, 33-37 and 40-42 is/are rejected.
- 7) ☒ Claim(s) 10-12, 25, 26, 31, 32, 38 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "72" has been used to designate two elements. It appears that the lower numeral should be "74." Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

In the specification, in paragraph [0034], "polyethylenetereph~~h~~thalate" is misspelled.

Appropriate correction is required.

Claim Objections

Claims 4, 5, 7, 9, 10, 11, 20, 22, 24-26, 30-32, 35, and 37-39 are objected to because of the following informalities:

With regard to claims 4, 5, 7, 10, 20, 22, and 25, the semicolons between Markush elements make it unclear where the listing ends. The Examiner suggests replacing it them with commas.

With regard to claims 7, 22, and 35, "polyethyleneterephthalate is misspelled.

With regard to claims 9-11, 24-26, 30-32, and 37-39, it is unclear how the "relaxed diameter" can be achieved if contraction is limited by support members that are part of the ring. In other words, it is unclear how there can be relaxed diameter if the device is incapable of contracting to that extent. Rather, it appears that the inner sizing member has the relaxed diameter; see paragraph [0035]. For this reason, the Examiner suggests claiming that the inner sizing member has a relaxed diameter and not the ring since the sizing member is resiliently biased even at a contracted diameter.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 9, 13-16, 18-20, 24, 28-30, 33, 34, 37, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Solem et al (US 6,210,432). Solem anticipates the claim language where a ring is formed or stretched into a larger size,

Art Unit: 3738

attached to a delivery apparatus and then attached to a valve annulus where it is returned to its smaller diameter; see Figures 2 to 11 and column 3, line 37 to column 4, line 55. Since Solem calls his device a U-shaped ring, the device is considered to be a ring to the extent that the art considers is so; see Figures 10 and 11 as well as column 4, lines 46-55. The attachment device as claimed is hook (10) on the ring body (8).

With regard to claim 2, the sizing member as claimed is string (9) and the attachment sheath as claimed is cover sheet (11).

With regard to claim 9, the counterforce of the tissue on the device would inherently prevent a fully relaxed diameter such that the claimed method is considered fully met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 27, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al (US 6,210,432) alone. Solem meets the claim language except fails to disclose the composition of the hooks and the composition of the other materials of the string. However, it is the Examiner's position that it would have been *prima facie* obvious to make the hooks of the same material as the strings in order to prevent electrolytic corrosion in the body. Similarly, it would have been obvious to make

the strings out of an elastomer to prevent any form of electrolytic corrosion since a simple spring material is all that is required to perform the function in Solem.

Claims 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem (US 6,210,432) in view of Tweden (US 5,895,419). Solem meets the claim language except fails to teach using sutures to attach the device to the annulus. However, Tweden teaches that it was known to the art to use hooks as alternatives to sutures; see column 3, lines 52-67. Therefore, it is the Examiner's position that it would have been obvious to use a suture in addition to the hooks of Solem to attach the device thereof in order to more securely attach the device to the annulus.

Claims 7, 22, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al (US 6,210,432) in view of Angell (US 4,042,979). Solem meets the claim language except fails to disclose the material used to make sheet (11). However, Angell teaches that it was known to make similar devices with sheets or sleeves out of polyethyleneterephthalate; see column 2, lines 44-49. Therefore, it is the Examiner's position that it would have been obvious to make the sheet of Solem out of polyethyleneterephthalate for the same reasons that Angell uses the same and so that the material used would be a material well known material to the art.

Claims 8, 23, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al (US 6,210,432) in view of Schwartz et al (US 2002/0099439). Solem meets the claim language except for the use of a medicament to coat the device to encourage ingrowth. However, Schwartz teaches that it was well known to coat similar device with medicaments in order to encourage ingrowth and attachment; see

Art Unit: 3738

paragraph [0014] and see also the seventh paragraph of provisional application 60/236,501. Therefore, it is the Examiner's position that it would have been obvious to coat the Solem device with the medicament of Schwartz in order to encourage ingrowth and attachment of the device long term, as implied by Schwartz.

Allowable Subject Matter

Claims 10, 11, 12, 25, 26, 31, 32, 38, and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The objected to language would have to be corrected as well before the claims could be allowed.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 3738

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a long horizontal flourish extending to the right.

Paul Prebilic
Primary Examiner
Art Unit 3738